

LEADER CASTOR OIL- castor oil oil

Cardinal Health

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Leader 078000 078AACastor Oil

Active ingredient

Castor oil USP 100%

Purpose

Stimulant Laxative

Use

For relief of occasional constipation (irregularity). Generally produces bowel movement in 6 to 12 hours.

Warnings

for this product

Do not use

for a period longer than 1 week

Ask a doctor before use if you have

- abdominal pain, nausea, or vomiting
- noticed a sudden change in bowel habits that persists over a period of 2 weeks

Ask a doctor or pharmacist before use if you are

taking any other drug. Take this product 2 or more hours before or after other drugs. Laxatives may affect how other drugs work.

Stop use and ask a doctor

if you have rectal bleeding or failure to have a bowel movement after use. These could be signs of a serious condition.

If pregnant or breast feeding

ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children over 12 years of age - 1 to a maximum of 4 tablespoons (15 to 60 mL) in a single daily dose

children 2 to under 12 years of age - 1 to a maximum of 3 teaspoons (5 to 15 mL) in a single daily dose

children under 2 years of age - do not use, consult a doctor

Other information

Keep tightly closed, away from excessive heat.

Adverse reactions

Dist. by CAH, Dublin, OH 43017

2019 Cardinal Health

CIN 5516034

078.000/078AA

principal display panel

LEADER

NDC 70000-0024-1

Castor

Oil

USP

Stimulant Laxative

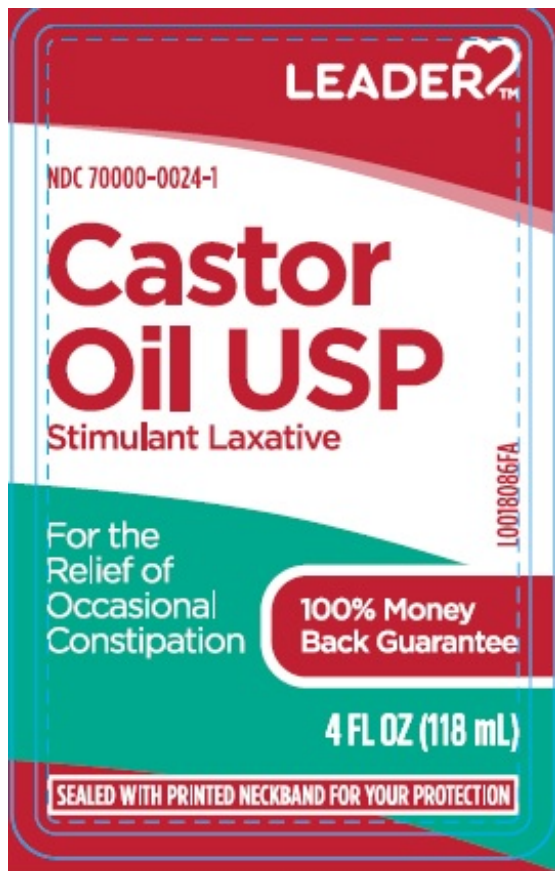
For the Relief of

Occasional Constipation

100% Money Back Guarantee

4 FL OZ (118 mL)

SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION



LEADER CASTOR OIL

castor oil oil

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70000-0024 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-------------|
| CASTOR OIL (UNII: D5340Y2I9G) (CASTOR OIL - UNII:D5340Y2I9G) | CASTOR OIL | 1 g in 1 mL |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:70000-0024-1 | 118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 03/12/2019 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC monograph not | cast224 | 03/12/2019 | |

| | | | |
|-------|----------|------------|--|
| final | part 554 | 05/12/2019 | |
|-------|----------|------------|--|

Labeler - Cardinal Health (097537435)

Registrant - Vi-Jon, LLC (790752542)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|-------------------------|
| Vi-Jon, LLC | | 790752542 | manufacture(70000-0024) |

Revised: 4/2021

Cardinal Health